



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/685,139

10/14/2003

Steve Mitchell

5910-187

4489

65901

7590

07/08/2009

MEDTRONIC

Attn: Noreen Johnson - IP Legal Department

2600 Sofamor Danek Drive

Memphis, TN 38132

EXAMINER

HOFFMAN, MARY C

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

07/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/685,139	Applicant(s) MITCHELL, STEVE	
	Examiner MARY HOFFMAN	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7, 26-56, 58-64, 66-81 and 83-85 is/are pending in the application.
- 4a) Of the above claim(s) 70-76 and 78-81 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7, 43-56, 58-64, 66-69 and 85 is/are allowed.
- 6) ☒ Claim(s) 26-37, 39-42, 77 and 83 is/are rejected.
- 7) ☒ Claim(s) 38 and 84 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The finality of the office action mailed 03/05/2009 has been vacated.

Allowable Subject Matter

Claims 7, 43-56, 58-64, 66-69 and 85 are allowed.

Claims 38 and 84 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The indicated allowability of claims 26-37, 39-42, 77 and 83 is withdrawn in view of the newly discovered reference(s) to Zucherman et al. (US. Pat. No. 6,451,019).

Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claim 42 is rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 42, lines 1-2, applicant positively recites part of a human, i.e. "a device that secures the base to an S1 vertebra". Thus claim 42 includes a human within their scope and is non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26, 29-37, 39-42, 77 and 83 are rejected under 35 U.S.C. 102(e) as being anticipated by Zucherman et al. (US. Pat. No. 6,451,019).

Zucherman et al. disclose an implant (see FIG. 131) adapted to be placed between vertebrae comprising: a body (2002, 2016, 2014); at least one hook (2008) extending from the body and including a first contact surface that faces in an inferior direction to allow the body to engage a first vertebra; a brace (2026,2024) extending from the body and including a distal end (2026) with a second contact surface that faces in a superior direction and an elongated section (2024) extending outward from the distal end that is secured to the body, the distal end including a greater thickness than the elongated section; and a device (2022) that secures the elongated section to the body and positions the second contact surface to contact an inferior surface of a spinous process of a second vertebra positioned superior of the first vertebra during extension of the vertebrae.

A part of the implant is titanium (col. 35, line 8). The device secures the brace to the body in a plurality of positions. The distal end is bulbous/round. The distal end

Art Unit: 3733

provides a surface which is at an angle to the elongated section, which surface is adapted to engage a L5 vertebra. The distal end provides a surface that is adapted to spread a contact load between a L5 vertebra and the distal end. The distal end is adapted to engage a spinous process of a L5 vertebra. The distal end is adapted to engage a spinous process of a L5 vertebra over a conforming contact area. The distal end includes a convex surface that is adapted to engage a spinous process of a L5 vertebra in order to spread the load between the distal end and the spinous process of the L5 vertebra. The body includes a first portion (2016) and second portion (2014) with a beam platform (2002) located between the first and second positions and the beam platform spaced from the first and second positions in order to space the brace from the first and second portions. The hook extends from the first portion and another hook extends from the second portion. The device (2022) extends from the platform. The implant includes a device (2012) that is capable of securing the base to an S1 vertebra. The second contact surface includes a convex surface that extends within a median plane of the implant.

Regarding claim 77, Zucherman et al. disclose an implant (see FIG. 131) adapted to be placed between vertebrae comprising: a body (2002); at least one hook (2008) extending from the body and adapted to allow the body to engage a first vertebra; a brace (2026,2024) extending from the body; the brace having a distal end (2026) with a curved surface with a first thickness and a beam (2024) with a second smaller thickness, wherein the curved surface is adapted to contact an inferior surface of a spinous process of a second vertebra; and a device (2022) that connects the beam

Art Unit: 3733

to the body to secure the brace to the body and positions the curved surface outward from the body to contact the inferior surface of the spinous process of the second vertebra during extension of the vertebrae.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zucherman et al. (US. Pat. No. 6,451,019).

Zucherman et al. disclose the claimed invention except for at least part of the implant being comprised of a material selected from the group consisting of: polyetheretherketone, polyaryletheretherketone, and polyetherketoneketone, or consisting of polyetherketoneetherketoneketone, ployetheretherketoneketone, polyketone, and polyetherketone. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Zucherman et al. with at least part of the implant being comprised of a material selected from the group consisting of: polyetheretherketone, polyaryletheretherketone, and polyetherketoneketone, or consisting of polyetherketoneetherketoneketone, ployetheretherketoneketone, polyketone, and polyetherketone, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARY HOFFMAN whose telephone number is (571)272-5566. The examiner can normally be reached on Monday-Thursday 10:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary C. Hoffman/
Examiner, Art Unit 3733

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738